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|-------------------------------|------------------------|---------------------|--|
| Notice of Allowability | Application No. | Applicant(s) | |
| | 09/724,569 | ANDERSON ET AL. | |
| | Examiner | Art Unit | |
| | Malgorzata A. Walicka | 1652 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. This communication is responsive to amendment of 04/05/05.
2. The allowed claim(s) is/are 56 and 61-77.
3. The drawings filed on _____ are accepted by the Examiner.
4. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some*
 - c) None
 of the:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) hereto or 2) to Paper No./Mail Date _____.
 - (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of

Paper No./Mail Date _____.
7. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. Notice of References Cited (PTO-892)
2. Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 04/05/05
4. Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. Notice of Informal Patent Application (PTO-152)
6. Interview Summary (PTO-413),
Paper No./Mail Date _____.
7. Examiner's Amendment/Comment
8. Examiner's Statement of Reasons for Allowance
9. Other _____.

Art Unit: 1652

The Amendment of April 5, 2005 and the second substitute sequence listing in the paper and computer readable form filed May 6, 2005 are acknowledged. Claim 56, 63, 72 and 73 have been amended; claim 57-59 have been canceled by this amendment. Claims 1-55 and 78-131 were previously canceled. Claims 56 and 60-77 are pending in the application; claim 60 is withdrawn from examiner's consideration as directed to the nonelected species. Claims 56 and 61-77 are under examination.

DETAILED ACTION

2. Objections

2.1. Oath

The objection to the oath is withdrawn because Applicants submit a copy the oath filed in declaration for USSN 09/501, 708, in accordance with 37 CFR 1.639(d)(1).

2.1. Specification

The objection to the specification is withdrawn, because the amendment has been filed.

3. Rejections

3.1. 35 USC, section 112, second paragraph

Rejection of claim 72-77 made in the previous Office Action is withdrawn, because the claims have been amended.

Art Unit: 1652

3.2. 35 USC, section 102

Rejection of claims 57-58 made under this section in the previous Office Action is moot, because the claims have been canceled.

Rejection of claims 56 and 61-68 under 35 U.S.C. 102(b) as being anticipated by US patent No. 6,319,689, issued to Powell et al. on Nov. 20, 2001, with priority date Jan. 28, 1997 is withdrawn, because the claims have been amended.

4. Examiner's amendment

An examiner's amendment to the record appears below.

(a) Please amend claim 56 to read:

56. An isolated nucleic acid, comprising a sequence of nucleotides that encode a β -secretase protein beginning at residue 46 and extending to position 452 of SEQ ID NO: 2 or up to several amino acids beyond but lacking a transmembrane region, or a completely complementary sequence thereof [of any of such nucleotides].

(b) Please cancel claim 60.

(c) Please amend claim 63:

In the first line replace "A heterologous cell" with --An isolated heterologous cell--.

(d) Please amend claim 73:

In the first line replace "A heterologous cell" with --An isolated heterologous cell--.

In part (ii) replace "is expressed" with --encodes a--.

(e) Please amend claim 75:

In the second line insert the conjunction "and" after " β -secretase protein".

Authorization for this examiner's amendment was given in a telephone interview with J. Liebeschuetz on August 31, 2005.

5. Allowance

Claims 56 and 61-77 are allowed. The following is the examiner reason for allowance.

Applicants disclosed human β -secretase set forth by SEQ ID NO: 2 of 501 amino acid residues, whose mature form consists of amino acid residues 46-501. Applicants determined that the fragment of SEQ ID NO: 2 consisting of amino acid residues 453-478 is a transmembrane fragment that is not necessary for the enzyme activity. The β -secretase claimed by the Applicants set forth by claim 56 is novel and nonobvious. Although the protein consisting of amino acids 1-501 and identical to SEQ ID NO: 2 of the instant application was disclosed in US patent No. 6, 420, 534, issued to Gurney et al., with priority date September 24, 1998, which is earlier than the priority date (June 15, 1999) of the instant application, the patent does not teach the transmembrane region of amino acid 453-478 of SEQ ID NO: 2. Gurney et al. teach a transmembrane domain, but they misidentify it as consisting of amino acid residues 392-417, which was proved first by the inventors and than also by others, to be in error. While a skilled artisan might have been motivated to prepare a fragment of the β -secretase of Gurney et al. lacking transmembrane domain, they would not have been motivated to select a fragment of Gurney et al. as claimed. As such the claimed nucleic acids are novel and non-obvious.

Art Unit: 1652

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Małgorzata A. Walicka whose telephone number is (571) 272-0944. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Malgorzata A. Walicka, Ph.D.

Art Unit 1652

Patent Examiner

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(60)